

**Amendment Under 37 C.F.R. § 1.116  
Expedited Procedure - Art Unit 1632****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Chiocca and Chung

Appl. No. 09/653,277

Filed: August 31, 2000

For: **Cell-Specific and/or Tumor-Specific  
Promoter Retargeting of Herpes  
Gamma 34.5 Gene Expression**

Confirmation No. 4747

Art Unit: 1632

Examiner: J. Woitach

Atty. Docket: 0609.4830002/JAG/KRM

**Declaration of E. Antonio Chiocca Under 37 C.F.R. § 1.132**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Mail Stop AF

Sir:

The undersigned, Dr. E. Antonio Chiocca, declares and states that:

1. I am a co-inventor of the above-captioned U.S. patent application.
2. I am an associate visiting neurosurgeon at the Massachusetts General Hospital (MGH) and associate professor of surgery at Harvard Medical School. In addition, I am the director of the Molecular Neuro-Oncology Laboratory (section of Neuro-Genetic Surgery) at MGH, where I conduct and supervise neurosurgical research in the fields of gene transfer, gene therapy, vector engineering, and neuro-genetic surgery.
3. I am the subject of the *Curriculum Vitae* attached as Exhibit 1. On the basis of the information and facts contained in this document, I submit that I am an expert in the fields of neurosurgery, neuro-genetic surgery, and neuro-oncology.
4. I have read and understand the Office Action dated May 20, 2003, Paper No. 17, particularly pages 5-10 in which the claims have been rejected under 35 U.S.C. § 112, first paragraph, for non-enablement of "other types of neoplastic cells" (aside from CNS and peruse metastatic liver and colon cancer) and "other promoters" (aside from B-myb).
5. Subsequent to the filing of the above-referenced patent application, I, together with other investigators, have obtained additional *in vitro* and *in vivo* experimental data, which demonstrate tumor-specific viral replication using (1) the nestin promoter; and (2) the prostate specific antigen (PSA) promoter, to drive expression of the herpes  $\gamma$ 34.5 gene.